UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,491	05/30/2000	Kurt Hertogs	TIBO-0016(VIP0004US)	8312

27777 7590 01/22/2008

PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
BORIN, MICHAEL L	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
01/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/580,491	HERTOGS ET AL.	
	Examiner	Art Unit	
	Michael Borin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 November 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Amendment filed 11/08/2007 is acknowledged.

Claim 7 is pending.

Claim Rejections - 35 USC § 103

Rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Condra et al. and admitted prior art, and de Bethune (US 6,221,578) and Seki et al. (Antiviral Chemistry & Chemotherapy (1995) 6(2), 73-9), and Bakhanashvili et al (FEBS Letters (1996), 391(3), 257-262) is maintained.

Condra reference has been used in the prior art rejections throughout preceding prosecution history. The reference addresses issues of resistance of HIV treatment to indinavir, HIV protease inhibitor. The reference evaluates effectiveness of antiviral therapy of HIV patients with protease inhibitor Indinavir (IDV). To evaluate the effectiveness of therapy with IDV, blood of HIV infected patients was collected (same step as step I) of the instant claim), and nucleic acids encoding HIV protease are examined (i.e., as in step (ii)(c) of claim 7. In one patient, patient "O", at least one mutation, namely 88T (i.e., the elected species) correlates with reduced effectiveness of antiviral therapy (see table 1, patient "O") - the resistance to IDV increased to over 3000 nM (see table 1, column IDV CIC and p. 8270, right col., lines 9-10 from bottom). The thus identified at least one mutation correlates with reduced effectiveness of IDV (which reads on step (iii) of the instant claim.

Note, that even though the instant claim 7, step c), recites various mutations, it is drawn to "at least one" mutation, and, therefore, it reads on situations wherein the recited mutation is one of several others.

Condra et al do not teach address resistance conferred by mutations in HIV reverse transcriptase as it addresses treatment with a protease inhibitor alone.

However as well accepted in the art, and as addressed in the Background section, p. 3, last full paragraph, the preferential HIV therapy includes combination of inhibitors of both PI and RT (reverse transcriptase), the latter can be also a combination of NNTRTI and NRTI. Therefore, it would be obvious to one skilled in the art at the time the invention made to evaluate effectiveness of such combined anti-HIV therapy by determining presence of potential resistance to RT inhibitors.

In regard to the latter, de Bethune et al teach that 101Q mutation in reverse transcriptase (i.e., one of the mutations listed in the instant claim 7 for the first nucleic acid) indicates phenotypical resistance to NNRTI (see Table 9, last line, and col. 18, last paragraph).

Likewise, Larder et al. teaches that 69S-[S-S] mutation (i.e., one of the mutations listed in the instant claim 7 for the second nucleic acid) confers résistance to NRTIs tep (a)(2)).

Further, Bakhanashvili et al (see p. 262, last full paragraph, p. 261, right column, first full paragraph) teach resistance to treatment by nucleoside analogs

conferred by Met 184 to Leu mutation in RT, i.e., another mutation addressed in the instant claim 7 with respect to the second nucleic acid.

Taken together, an artisan would be motivated to evaluate effectiveness of anti-HIV therapy by determining presence of potential resistances to both PI and RT inhibitors, i.e., inhibitors used in combination as a part of routine HIV therapy . In the course of assessing potential mutations, an artisan would be motivated to determine mutations described in Condra, de Bethune, Larder et al. and Bakhanashvili as these mutations are some of the mutations conferring resistance to known HIV PI or RT inhibitors.

Response to arguments

Applicant argues that there is no suggestion in the references with respect to specific combination in claim 7. Examiner disagrees with addressing the mutations addressed in the claim as "specific combination". The claim is directed to evaluating the effectiveness of an[y] antiviral therapy whereby three different types of mutations are identified (correlating with resistance to NNRTI, NRTI, or PI) and presence of any one of the mutations correlates with effectiveness of said an[y] antiviral therapy. Each of said mutations, in turn, comprises at least one of plurality mutations for the particular resistance type. Therefore, there are no "specific combination" of mutations addressed in the claims.

Further, applicant argues that there would be no motivation to combine the references. Examiner disagrees. The claims as amended are directed to identifying any one mutation and to correlate it with effectiveness of any kind of antiviral therapy. As HIV therapy includes combination of inhibitors of both PI and RT (reverse transcriptase; the latter can be also a combination of NNRTI and NRTI), it would be obvious to an artisan to evaluate possible mutations reducing effectiveness of any of those therapies. All the claimed elements were known, in the prior art, and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded nothing more than predictable results to one of ordinary skill in the art at the time of the invention.

It is also noted that the claim is amended to remove all "at least one" phrases. At the same time the claim is amended to recite that although three nucleic acids are to be determined, presence of any one of them is correlated with the effectiveness of antiviral therapy. Thus, combining references teaching identifying different mutations is justified as long as any of these identified mutations lead to evaluating of effectiveness of any prongs of known combination therapies.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Borin, Ph.D.
Primary Examiner
Art Unit 1631

mlb